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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/996,658 | 11/29/2001 | James M. Coull | 027232-000910US | 5256 |
| 20350 | 7590 | 11/14/2008 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP | | | SISSON, BRADLEY L | |
| TWO EMBARCADERO CENTER | | | | |
| EIGHTH FLOOR | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/996,658 | COULL ET AL. | |
| | Examiner | Art Unit | |
| | Bradley L. Sisson | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 August 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,4-8,11,15-18,21-26,29,36,38-43 and 46-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,4-8,11,15-18,21-26,29,36,38-43 and 46-48 is/are rejected.

7) Claim(s) 5,6,22,23,39 and 40 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 5, 6, 22, 23, 39, and 40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.
2. Claims 5 and 6 depend from claim 4; claims 22 and 23 depend from claim 21; and claims 39 and 40 depend from claim 38. Each of claims 4, 21, and 38 require "the detectable molecular probe is not labeled with a detectable moiety." Said language has been construed as encompassing both direct and indirect labeling. Claims 5, 22, and 39 seemingly broaden the scope of claims 4, 21, and 38 by having a detectable moiety being bound to the unlabeled detectable molecular probe via an antibody linker. Claims 6, 23, and 40 depend from said claims 5, 22, and 39, respectively, and fail to overcome this issue and are thusly, similarly objected.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1, 4-8, 11, 15-18, 21-26, 29-31, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 has been amended so to now read in part: “A method for determining the presence of a microbial organism of interest in a sample *from another organism or organisms to be distinguished...*” (Emphasis added.) Seemingly, the claim is now redundant in that one is determining the presence of a microbe and also distinguishing it from other organisms. Claims 4-8, 11, and 15-17, which depend from claim 1, fail to overcome this issue and are similarly rejected.

6. Claim 18 has been found to provide antecedent support for “detectable or independently detectable molecular probes,” however, said claim has not been found to provide antecedent support for “the detectable or independently detectable organisms.” Additionally, claim 18 has not been found to provide antecedent support for “the presence, absence, or number of detectable organisms.” Claims 21-26 and 29-31, which depend from claim 18, fail to overcome these issues, and therefore, are similarly rejected.

7. Claim 35 has been found to provide antecedent support for “detectable or independently detectable molecular probes,” however, said claim has not been found to provide antecedent support for “the detectable or independently detectable organisms.” Additionally, claim 35 has not been found to provide antecedent support for “the presence, absence, or number of detectable organisms.” Claims 38-43 and 46-48, which depend from claim 35, fail to overcome these issues, and therefore, are similarly rejected.

8. Claim 35 recites the limitation “the same stain” in line 8. There is insufficient antecedent basis for this limitation in the claim. Claims 38-43 and 46-48, which depend from claim 35, fail to overcome this issue and are similarly rejected.

9. Claims 4-6, 21-23, and 38-40 are indefinite with respect to what constitutes the metes and bounds of “detectable molecular probe.” As set forth in claims 4, 21, and 38, the “detectable molecular probes” are unlabeled. If the probes are all unlabeled, it is less than clear as to how they are also “detectable.” In accordance with the method, the “detectable probes” are ultimately labeled with a marker bound to an antibody, wherein the antibody binds to the unlabeled probes. As noted above, the aspect of linking a label to the probes is deemed to exceed the requirement that the probes remain unlabeled. Claims 5, 6, 22, 23, 39, and 40, which depend from said claims 4, 21, and 38, fail to overcome this issue and are similarly rejected.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 4-8, 11, 15-18, 21-26, 29-31, 35, 38-43, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,110,676 (Coull et al.) in view of US Patent 5,612,458 (Hyldig-Nielsen et al.), and US Patent 5,225,584 (Brooks et al.).

14. Coull et al., disclose and claim a method of determining the presence of a nucleic acid in a sample. As set forth on column 1, probe assays have been used to detect bacteria, fungi, virus-applicant's "microbes."

15. Coull et al., teach that the hybridization reaction comprises the use of peptide nucleic acid (PNA) probes that are detectable yet unlabeled. The aspect of using antibodies to detect the presence of PNA – target duplexes is disclosed.

16. Coull et al., makes reference to US Patent 5,612,458 (Hyldig-Nielsen et al.)

17. Hyldig-Nielsen et al., disclose the development and use of antibodies that bind specifically to PNA:DNA as well as PNA:RNA duplex structures, and how these antibodies can be used to detect the presence of target nucleic acids.

18. Brooks et al., column 18, bridging to column 19, discloses the development and use of various chemiluminescent labels, and that these labels can be used in combination with immunoassays as well as nucleic acid hybridization assays. The applicability of the labels to the

assays and their use with supports that can take the form of arrays as well as membranes, beads, microtiter plates is specifically disclosed.

19. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Coull et al., which includes the use of antibodies that bind to the PNA-DNA or PNA:RNA complex, by use of a solid support such as those identified by Brooks. As such would have accorded the ordinary artisan with an efficient, sensitive, and reproducible method of detection. In view of the detailed teachings of the prior art of record, said ordinary artisan would have had a most reasonable expectation of success.

Conclusion

20. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634